

APPENDIX C: ALLOWABLE AND EXCLUDED COSTS FOR THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

The FD&C Act as amended defines the “process for the review of human drug applications” and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. The Agency identifies those activities that are applicable to the process for the review of human drug applications in this appendix. In Appendix D, the Agency describes how the costs for the process for the review of human drug applications are developed, based on the allowable activities identified in this appendix.

Because over 96 percent of the amounts obligated by FDA each year are expended within two years, obligations represent an accurate measure of costs.

PDUFA RELATED COSTS

Included Activities

Section 735(6) of the FD&C Act defines in general terms the activities necessary for the review of human drug applications (the “human drug review process”). In summary, costs related to the following process activities have been attributed to the process for the review of human drug applications:

- All investigational new drug review activities, including amendments;
- All review activities for NDAs, BLAs, including supplements and amendments;
- Regulation and policy development activities related to the review of human drug applications;
- Development of product standards for products subject to review and evaluation;
- Meetings between FDA and the sponsor of a covered application or supplement;
- Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising;
- Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval;
- Inspections of facilities undertaken as part of the review of pending applications or supplements;
- Lot release activities for covered biological products;
- Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products;
- Monitoring of clinical and other research conducted in connection with the review of human drug applications;
- User Fee Act implementation activities;
- Research related to the human drug review process; and
- Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities: collecting, developing,

and reviewing safety information on approved drugs, including adverse event reports; developing and using improved adverse event data-collection systems, including information technology systems; developing and using improved analytical tools to assess potential safety problems, including access to external data bases; implementing and enforcing section 505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies); and carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).

All user-fee-related costs represented by the above activities are collectively referred to in this report as costs for the process for the review of human drug applications.

Section 735(7) of the FD&C Act defines the “costs of resources allocated for the process for the review of human drug applications” as the expenses incurred in connection with this process for:

- (A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to such officers, employees, committees, and contracts;
- (B) management of information, and the acquisition, maintenance, and repair of computer resources;
- (C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and
- (D) collecting user fees under section 736 of the FD&C Act and accounting for resources allocated for the review of human drug applications and supplements.

Excluded Activities

The FD&C Act excludes costs related to the following:

Excluded Products

- Generic drugs
- Over-the-counter drugs not associated with an NDA or NDA supplement
- Large volume parenteral drug products approved before September 1, 1992
- Allergenic extract products
- Whole blood or a blood component for transfusion
- In vitro diagnostic biologic products
- Certain drugs derived from bovine blood

Excluded Process Activities

- Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act
- Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act
- Advertising review activities once marketing of the product has begun
- Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act
- Research unrelated to the human drug review process